DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 23, 2015

Stryker Instruments
Ms. Brittney M. Larsen, RAC
Senior Regulatory Affairs Representative
4100 E. Milham Ave.
Kalamazoo, Michigan 49001

Re: K143320
Trade/Device Name: Stryker Elite and Heavy Duty (HD) Attachments
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class: Class II
Product Code: HBE, HBB, ERL, DZI
Dated: March 20, 2015
Received: March 24, 2015

Dear Ms. Larsen,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143320

Device Name
Stryker Elite and Heavy Duty (HD) Attachments

Indications for Use *(Describe)*
The Elite and Heavy Duty Attachments are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE) console and electric and pneumatic motors. When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut bone and bone cement in the following manner: drilling, reaming, decorticating, shaping, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose and Throat (ENT)/Otology/Neurotology/Otorhinolaryngology; Craniofacial and Maxillofacial; Dental; and Endoscopic applications.

The specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine.

When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut teeth in the following manner: sectioning, segmenting, splitting, fragmenting, extracting, removing, drilling, and reaming.

When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices, or the cutting of screws, metal, wires, pins, and other fixation devices in the following manner: sectioning, deburring, smoothing or shaping of metal, and removing/rounding sharp edges.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) Summary

| ***Contact Details*** | | | |
|---|---|---|---|
| **510(k) Owner** | Stryker Instruments<br>4100 E. Milham Avenue<br>Kalamazoo, Michigan 49001 USA<br>Ph: +1-269-323-5293<br>Fax: +1-269-324-5412 | | |
| **FDA Establishment Registration No.** | 1811755 | | |
| **Contact Person** | Brittney M. Larsen, RAC<br>Ph: +1-269-389-5293<br>Fax: +1-269-389-5412<br>Brittney.Larsen@Stryker.com | | |
| **Date Submitted** | April 22, 2015 | | |
| ***Device Name*** | | | |
| **Trade Name** | Stryker® Elite and Heavy Duty (HD) Attachments | | |
| **Common Name** | Surgical Drill Handpieces | | |
| **Classification** | II | | |
| **Primary Classification Name** | *Drills, Burs, Trephines & Accessories (Simple, Powered)*<br>(21 CFR 882.4310, Product code HBE) | | |
| **Secondary Classification Name** | *Drill, Surgical ENT (Electric or Pneumatic) including Handpiece*<br>(21 CFR 874.4250, Product code ERL) | | |
| | *Pneumatic cranial drill motor*<br>(21 CFR 882.4370, Product code HBB) | | |
| | *Drill, Bone, Powered*<br>(21 CFR 872.4120, Product code DZI) | | |
| ***Legally Marketed Predicate Device(s)*** | | | |
| **510(k) Number** | **Product Code** | **Trade Name** | **Manufacturer** |
| *Primary Predicate* | | | |
| K112593 | ERL (primary)<br>DZI, DZJ, HBE (secondary) | Stryker® Consolidated Operating Room Equipment (CORE) System | Stryker Instruments |
| *Secondary Predicate* | | | |
| K041754 | HBB (primary)<br>ERL, HBE (secondary) | Stryker Maestro Pneumatic System | Stryker Instruments |

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## Purpose of this Traditional 510(k) Premarket Notification

Stryker submits this Traditional 510(k), for the Stryker® Elite and HD Attachments, to request clearance for an expansion of indications and addition of color bands to the predicate devices. The predicate devices are currently cleared for a variety of general indications for use. The subject changes include adding the following specific procedures (hereafter referred to as medical applications): Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Transnasal/Transphenoidal, and Orthopedic Spine. This expansion of indications does not change the intended use or the fundamental scientific technology of the predicate devices. The subject modifications of this submission also include the addition of color bands to enhance the distinction of attachment and cutting accessory compatibility.

## Device Description and Intended Use

The Stryker® Elite and HD Attachments are used within a system consisting of a variety of devices, including a console, powered motors, and cutting accessories. The attachments connect to the motors and the cutting accessories to complete the system for physician use. The Stryker® Elite and HD Attachments are offered for prescription use only. The Elite and HD Attachments are intended to serve as interfaces between powered motors and cutting accessories for the purposes of:

- Cutting bone, bone cement, and teeth;
- Placing or cutting screws, metal, wires, pins, and other fixation devices; and
- Providing a location for the user to hold and grip the device system.

The Elite and HD Attachments are provided in straight and angled configurations. The subject Elite Attachments are offered in the following lengths: 7cm, 12cm, 14cm, 17cm, and 20cm. The Stryker® HD Attachments are offered in the following lengths: 9cm and 14cm.

The Elite and HD Attachments are powered by, and compatible with, the Stryker electric and pneumatic motors. The attachments are also used with the cutting accessories (burs). All the attachments demonstrate a rotary mode of action by transmitting torque.

The Elite and HD Attachments are made of stainless steel (SST). The attachments display a color band on the outer surface. The color bands serve to enhance the distinction of attachment and cutting accessory compatibility. The Elite and HD Attachment outer profiles feature a sleeker design. The Elite and HD Attachment outer surface textures include laterally grooved and continuous knurling textures for improved user grip.

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The Elite and HD Attachments are reusable, provided non-sterile, and end user sterilized. The attachments may be cleaned by manual or mechanical (automated) cleaning procedures. The attachment end user sterilization method is moist heat (steam) and the sterility assurance level (SAL) is $10^{-6}$. The Elite and HD Attachments have an expected life of one (1) year. The attachments are individually packaged in a sealed retention insert. The attachment labels contain a label specified part description, quantity, lot number, and contact information. There are no known contraindications for the Elite and HD Attachments.

## Indications for Use

The Elite and Heavy Duty Attachments are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) console and electric and pneumatic motors. When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut bone and bone cement in the following manner: drilling, reaming, decorticating, shaping, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose and Throat (ENT)/Otology/Neurotology/Otorhinolaryngology; Craniofacial and Maxillofacial; Dental; and Endoscopic applications.

The specific applications include Craniotomy/Craniectomy, Laminotomy/ Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine.

When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut teeth in the following manner: sectioning, segmenting, splitting, fragmenting, extracting, removing, drilling, and reaming.

When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices, or the cutting of screws, metal, wires, pins, and other fixation devices in the following manner: sectioning, deburring, smoothing or shaping of metal, and removing/rounding sharp edges.

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**Table 6-1. Comparison to predicate devices**

| Description | Stryker® CORE System (Primary Predicate - K112593) | Stryker Maestro Pneumatic System (Secondary Predicate - K041754) | Stryker® Elite and HD Attachments (Subject) | Explanation of Differences |
|---|---|---|---|---|
| Classification | Class II | | Class II | Identical |
| Primary Product Code | ERL<br>*Drill, Surgical, ENT (Electric or Pneumatic) including Handpiece* | HBB<br>*Pneumatic cranial drill motor* | HBE<br>*Drills, Burs, Trephines & Accessories (Simple, Powered)* | Equivalent |
| Primary Regulation | 21 CFR 874.4250<br>*Ear, nose, and throat electric or pneumatic surgical drill* | 21 CFR 882.4370<br>*Pneumatic cranial drill motor* | 21 CFR 882.4310<br>*Powered simple cranial drills, burrs, trephines, and their accessories.* | Equivalent |
| Product Types | Straight and angled attachments | | Straight and angled attachments | Identical |
| Conditions for Use | Reusable | | Reusable | Identical |
| Mechanism of Action | Powered by electric motors | Powered by pneumatic motors | Powered by electric and pneumatic motors | Equivalent |
| Mode of Action | Rotary (transmits torque) | | Rotary (transmits torque) | Identical |
| Expected Life | 1 year | | 1 year | Identical |
| Type of Use | Prescription use only | | Prescription use only | Identical |
| Intended Use | To serve as an interface between powered motors and cutting accessories for the purposes of:<br>• Cutting bone, bone cement, and teeth;<br>• Placing or cutting screws, metal, wires, pins, and other fixation devices;<br>• Providing a location for the user to hold and grip device system. | | To serve as an interface between powered motors and cutting accessories for the purposes of:<br>• Cutting bone, bone cement, and teeth;<br>• Placing or cutting screws, metal, wires, pins, and other fixation devices;<br>• Providing a location for the user to hold and grip device system. | Identical |

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| Descript-ion | Stryker® CORE System (Primary Predicate - K112593) | Stryker Maestro Pneumatic System (Secondary Predicate - K041754) | Stryker® Elite and HD Attachments (Subject) | Explanation of Differences |
|---|---|---|---|---|
| Indications for Use | The Stryker® Consolidated Operating Room Equipment (CORE) System is intended for use in the cutting, drilling, reaming, decorticating, shaping , and smoothing of bone, bone cement and teeth in a variety of surgical procedures, including but not limited to, dental, ENT (ear, nose, throat), neuro, spine, and endoscopic applications. It is also usable in the placement or cutting of screws, metal, wires, pins, and other fixation devices. | The Stryker Maestro Pneumatic system is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear, Nose and Throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries. | The Elite and Heavy Duty Attachments are intended to be used with the Stryker Consolidated Operating Room Equipment (CORE®) console and electric and pneumatic motors. When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut bone and bone cement in the following manner: drilling, reaming, decorticating, shaping, and smoothing for the following medical applications: Neuro; Spine; Ear, Nose and Throat (ENT)/Otology/ Neurotology/Otorhinolaryngology; Craniofacial and Maxillofacial; Dental; and Endoscopic applications.<br><br>The specific applications include Craniotomy/Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Endoscopic/Transnasal/Transphenoidal, and Orthopedic Spine.<br><br>When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are intended to cut teeth in the following manner: sectioning, segmenting, splitting, fragmenting, extracting, removing, drilling, and reaming.<br><br>When used with these motors, the Elite and Heavy Duty Attachments and Cutting Accessories are also usable in the preparation for the placement of screws, metal, wires, pins, and other fixation devices, or the cutting of screws, metal, wires, pins, and other fixation devices in the following manner: sectioning, deburring, smoothing or shaping of metal, and removing/rounding sharp edges. | The subject devices add the following indications for use to the existing, cleared indications: Craniectomy, Laminotomy/Laminectomy, Minimally Invasive Surgery (MIS) Spine, Expanded Endonasal Approach (EEA)/Anterior Skull Base/Transnasal/ Transphenoidal, and Orthopedic Spine. The subject indications add verbiage that defines cutting for each medium in the variety of surgical procedures listed. The purpose of the changes made to the indications for use is to list the procedures within each general indication as per current standard of care as known by the medical community. Verification and validation testing conducted has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices. |

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| Description | Stryker® CORE System (Primary Predicate - K112593); and Stryker Maestro Pneumatic System (Secondary Predicate - K041754) | Stryker® Elite and HD Attachments (Subject) | Explanation of Differences |
|---|---|---|---|
| *Size Information* | | | |
| Straight and Angled Attachment Length Offerings | 7cm, 9cm, 12cm, 14cm, 17cm (straight only), 20cm | 7cm, 9cm, 12cm, 14cm, 17cm, 20cm | Added the Elite 14cm Hooded and the Elite 17cm Angled Attachment offerings for marketing of a more competitive product offering. Both of the added attachments are within the cleared length range. The 14cm hooded attachment includes a built in hood. Verification and validation testing conducted has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices. |
| Attachment Rear Housing Outer Diameters | 0.677in (nominal) | 0.677in (nominal) | Identical |
| Attachment Nose Tube Outer Diameters | 0.234in (nominal)<br>0.299in (nominal) | 0.234in (nominal)<br>0.299in (nominal) | Identical |
| *Human Factors Information* | | | |
| Attachment Outer Profiles | Differences in outer attachment profile widths are pronounced | Differences in outer attachment profile widths are not pronounced | Changed the attachment outer profiles to achieve a sleeker design. These profile changes improve motor system balance. Verification and validation testing conducted has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices. |
| Attachment Outer Surface Texture | Continuous knurling texture | Continuous and laterally grooved knurling textures | Added laterally grooved knurling outer surface textures to attachments. This change improves user grip. Verification and validation testing conducted has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices. |
| *Patient Contacting Information* | | | |
| Attachments | Stainless Steel (SST) | SST | Identical |
| Color band identification | No color band | Color band | Added color bands to enhance the distinction of attachment and cutting accessory compatibility. Biocompatibility, verification, |

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| Description | Stryker® CORE System (Primary Predicate - K112593); and Stryker Maestro Pneumatic System (Secondary Predicate - K041754) | Stryker® Elite and HD Attachments (Subject) | Explanation of Differences |
|---|---|---|---|
| | | | and validation testing conducted has demonstrated that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices. |
| *General Information* | | | |
| Packaging | Packaged in a sealed retention insert | Packaged in a sealed retention insert | Identical |
| Labeling | Label specified part description, quantity, lot number, and contact information.<br>No known contraindications. | Label specified part description, quantity, lot number, and contact information.<br>No known contraindications. | Identical |
| *Sterilization Information* | | | |
| Attachments | End-user sterilized (provided non-sterile) | End-user sterilized (provided non-sterile) | Identical |
| Sterilization Method | Moist heat (steam) | Moist heat (steam) | Identical |
| Sterility Assurance Level (SAL) | $10^{-6}$ | $10^{-6}$ | Identical |
| *Cleaning Information* | | | |
| Cleaning Methods | Manual and mechanical (automated) | Manual and mechanical (automated) | Identical |

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**Performance Testing Summary**

Biocompatibility testing was performed on the subject devices in accordance with AAMI/ANSI/ISO ISO 10993-1:2009/(R)2013, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,* and Guidance for Industry and FDA Staff, *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,"* dated April 23, 2013. Results of testing validate that the subject devices are non-cytotoxic, non-sensitizing, a negligible irritant, non-toxic, and non-pyrogenic.

Functional life verification testing was performed to demonstrate the continued device performance during subject attachment life. Bur whip and bur chatter verification testing was conducted to verify the amplitude of bur whip and bur chatter for the subject attachments.

Packaging verification testing was performed as per ASTM D4169, *Standard practice for performance testing of shipping containers and systems (sterility)*. Results of testing validate package integrity during transport.

See **Table 6-4**, for a summary of the performance testing and acceptance criteria used to evaluate the subject devices. Stryker has determined that the subject devices have a similar safety and effectiveness profile as the legally marketed predicate devices.

**Table 6-4. Non-clinical testing and Biocompatibility Testing summary**

| Tests Performed | Biocompatibility Test | Conclusions |
|---|---|---|
| **Biocompatibility Testing** | Cytotoxicity | Non-cytotoxic |
| | Sensitization | Non-sensitizing |
| | Irritation | Negligible irritant |
| | Acute Systemic Toxicity | Non-toxic |
| | Material Mediated Pyrogenicity | Non-pyrogen |
| | Colorant Leachables | Pass |
| **Life Verification Testing** | Run time of 1 year | Pass |
| | 1 year of Autoclave cycles | Pass |
| | 1 year of Automatic wash cycles | Pass |
| | 1 year of Locking mechanism actuations – with drill | Pass |
| | 1 year of Locking mechanism actuations – with bur (cutting accessory) | Pass |
| | Maximum surface temperature on attachment during end of life evaluation ≤ 46ºC | Pass |

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| Tests Performed | Biocompatibility Test | Conclusions |
|---|---|---|
| **Bur Whip Verification Testing** | Mean whip ≤ 0.63mm | Pass |
| | Mean whip ≤ 0.30mm | Pass |
| **Bur Chatter Verification Testing** | Mean bur deflection ≤ 1.28mm | Pass |
| **Packaging Testing** | Package must maintain the product within its confines. Labels must remain attached and legible. | Pass |
| | The packaging may exhibit minimal damage. | Pass |
| | Product aesthetics should not be compromised and the product must be fully functional after this test procedure. | Pass |

**Clinical Testing**

No clinical testing was deemed necessary for this 510(k) premarket notification.

**Conclusion / Substantial Equivalence (SE) Rationale**

The intended use, basic design, functional characteristics, and fundamental scientific technology are identical between the subject Stryker® Elite and HD Attachments and predicate devices. The Stryker® Elite and HD Attachments have a similar safety and effectiveness profile as the legally marketed predicate devices.